

## General

### Guideline Title

The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia.

### Bibliographic Source(s)

American Psychiatric Association (APA). The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. Arlington (VA): American Psychiatric Association (APA); 2016. 210 p. [209 references]

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

The definitions for the strength of the recommendations (recommendation [1] or suggestion [2]) and the strength of evidence (high [A], moderate [B], or low [C]) are provided at the end of the "Major Recommendations" field.

Note: Throughout this guideline, the Guideline Writing Group uses the term *dementia*, which was used in the evidence that was considered in developing these recommendations. These recommendations are also meant to apply to individuals with major neurocognitive disorder, as defined in the American Psychiatric Association (APA) *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-5).

#### Guideline Statements

##### Assessment of Behavioral/Psychological Symptoms of Dementia

Statement 1. APA recommends that patients with dementia be assessed for the type, frequency, severity, pattern, and timing of symptoms. (1C)

Statement 2. APA recommends that patients with dementia be assessed for pain and other potentially modifiable contributors to symptoms as well as for factors, such as the subtype of dementia, that may influence choices of treatment. (1C)

Statement 3. APA recommends that in patients with dementia with agitation or psychosis, response to treatment be assessed with a quantitative measure. (1C)

#### Development of a Comprehensive Treatment Plan

Statement 4. APA recommends that patients with dementia have a documented comprehensive treatment plan that includes appropriate person-centered nonpharmacological and pharmacological interventions, as indicated. (1C)

#### Assessment of Benefits and Risks of Antipsychotic Treatment for the Patient

Statement 5. APA recommends that nonemergency antipsychotic medication should only be used for the treatment of agitation or psychosis in patients with dementia when symptoms are severe, are dangerous, and/or cause significant distress to the patient. (1B)

Statement 6. APA recommends reviewing the clinical response to nonpharmacological interventions prior to nonemergency use of an antipsychotic medication to treat agitation or psychosis in patients with dementia. (1C)

Statement 7. APA recommends that before nonemergency treatment with an antipsychotic is initiated in patients with dementia, the potential risks and benefits from antipsychotic medication be assessed by the clinician and discussed with the patient (if clinically feasible) as well as with the patient's surrogate decision maker (if relevant) with input from family or others involved with the patient. (1C)

#### Dosing, Duration, and Monitoring of Antipsychotic Treatment

Statement 8. APA recommends that if a risk/benefit assessment favors the use of an antipsychotic for behavioral/psychological symptoms in patients with dementia, treatment should be initiated at a low dose to be titrated up to the minimum effective dose as tolerated. (1B)

Statement 9. APA recommends that if a patient with dementia experiences a clinically significant side effect of antipsychotic treatment, the potential risks and benefits of antipsychotic medication should be reviewed by the clinician to determine if tapering and discontinuing of the medication is indicated. (1C)

Statement 10. APA recommends that in patients with dementia with agitation or psychosis, if there is no clinically significant response after a 4-week trial of an adequate dose of an antipsychotic drug, the medication should be tapered and withdrawn. (1B)

Statement 11. APA recommends that in a patient who has shown a positive response to treatment, decision making about possible tapering of antipsychotic medication should be accompanied by a discussion with the patient (if clinically feasible) as well as with the patient's surrogate decision maker (if relevant) with input from family or others involved with the patient. The aim of such a discussion is to elicit their preferences and concerns and to review the initial goals, observed benefits and side effects of antipsychotic treatment, and potential risks of continued exposure to antipsychotics, as well as past experience with antipsychotic medication trials and tapering attempts. (1C)

Statement 12. APA recommends that in patients with dementia who show adequate response of behavioral/psychological symptoms to treatment with an antipsychotic drug, an attempt to taper and withdraw the drug should be made within 4 months of initiation, unless the patient experienced a recurrence of symptoms with prior attempts at tapering of antipsychotic medication. (1C)

Statement 13. APA recommends that in patients with dementia whose antipsychotic medication is being tapered, assessment of symptoms should occur at least monthly during the taper and for at least 4 months after medication discontinuation to identify signs of recurrence and trigger a reassessment of the benefits and risks of antipsychotic treatment. (1C)

#### Use of Specific Antipsychotic Medications, Depending on Clinical Context

Statement 14. APA recommends that in the absence of delirium, if nonemergency antipsychotic medication treatment is indicated, haloperidol should not be used as a first-line agent. (1B)

Statement 15. APA recommends that in patients with dementia with agitation or psychosis, a long-acting injectable antipsychotic medication should not be utilized unless it is otherwise indicated for a co-occurring chronic psychotic disorder. (1B)

### Definitions

#### Rating the Strength of the Recommendations

"Recommendation" (denoted by the numeral 1 after the guideline statement) indicates confidence that the benefits of the intervention clearly outweigh the harms.

"Suggestion" (denoted by the numeral 2 after the guideline statement) indicates uncertainty (i.e., the balance of benefits and harms is difficult to judge, or either the benefits or the harms are unclear).

#### Rating the Strength of Supporting Research Evidence

High (denoted by the letter *A*) = High confidence that the evidence reflects the true effect. Further research is very unlikely to change confidence in the estimate of effect.

Moderate (denoted by the letter *B*) = Moderate confidence that the evidence reflects the true effect. Further research may change confidence in the estimate of effect and may change the estimate.

Low (denoted by the letter *C*) = Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is likely to change the estimate.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Dementia with agitation or psychosis

### Guideline Category

Assessment of Therapeutic Effectiveness

Evaluation

Management

Treatment

### Clinical Specialty

Family Practice

Geriatrics

Neurology

Psychiatry

## Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To improve the care of patients with dementia who are exhibiting agitation or psychosis

## Target Population

Individuals with dementia in all settings of care with care delivered by generalist and specialist clinicians

Note: Recommendations regarding treatment with antipsychotic medications are not intended to apply to individuals who are receiving antipsychotic medication for another indication (e.g., chronic psychotic illness) or individuals who are receiving an antipsychotic medication in an urgent context.

## Interventions and Practices Considered

1. Assessment of behavioral/psychological symptoms of dementia
  - Assessment for type, frequency, severity, pattern, and timing of symptoms
  - Assessment for pain and other factors contributing to symptoms
  - Use of quantitative measures to assess response to treatment
2. Development of a comprehensive treatment plan incorporating pharmacological and non-pharmacological interventions
3. Assessment of benefits and risk of antipsychotic treatment for the patient
4. Dosing, duration, and monitoring of antipsychotic treatment
  - Use of low doses in initial treatment
  - Tapering and discontinuation
  - Assessment of symptoms of relapse
5. Use of specific antipsychotic medication, depending on clinical context (haloperidol not recommended as first-line agent; long-acting injectable medications not recommended unless otherwise indicated for comorbid psychiatric disorder)

## Major Outcomes Considered

- Effect of antipsychotic medications on symptoms of agitation and psychosis
- Degree of improvement as measured by scores on quantitative rating scales such as CMAI (Cohen-Mansfield Agitation Inventory), MMSE (Mini-Mental State Exam), NPI (Neuropsychiatric Inventory), BEHAVE-AD (Behavioral Pathology in Alzheimer's Disease), CGI-C Clinical Global Impression of Change), NRS (Neurobehavioral Rating Scale), and others
- Quality of life
- Treatment discontinuation rates
- Relapse rates
- Adverse effects/harms of treatment

## Methodology

### Methods Used to Collect/Select the Evidence

## Description of Methods Used to Collect/Select the Evidence

### Systematic Review Methodology

This guideline is based on a systematic search of available research evidence. See the supplemental data (see the "Availability of Companion Documents" field) for search terms and limits used in the searches.

Initial searches of MEDLINE, PsycINFO, and Cochrane databases were conducted in February 2013 and included search terms for second-generation antipsychotics (SGAs) and for off-label indications for SGA use (including dementia), extending the search conducted for the Agency for Healthcare Research and Quality (AHRQ) systematic review "Off-Label Use of Atypical Antipsychotics: An Update" (Maglione et al. 2011). These searches yielded 1,624 articles in MEDLINE, 657 articles in PsycINFO, and 1,457 articles in the Cochrane database. Two individuals screened the 2,141 articles from the different searches when duplicate references were eliminated. Included articles were a clinical trial (including a controlled or randomized trial), observational study, meta-analysis, or systematic review that was clinically relevant to the off-label use of SGAs. The identified articles were subsequently restricted to the topic of dementia, and this yielded 12 articles (3 randomized trials, 9 observational studies).

Subsequent systematic searches were conducted in January 2015 and included terms for all antipsychotic medications and for all types of dementia, cognitive disorders, and cognitive impairment. Searches were limited to English language articles in adult humans and to clinical trials, observational studies, meta-analyses, and systematic reviews. All searches were done for the years from 1900 through 2014. These searches yielded 1,483 articles in MEDLINE, 470 articles in PsycINFO, and 335 articles in the Cochrane database. After duplicate articles and unpublished meeting abstracts were removed, two individuals screened an additional 1,719 articles for relevance to the use of antipsychotic medications in individuals with dementia. Articles were included if they were randomized controlled trials that related to antipsychotic treatment of behavioral and psychological symptoms of dementia (BPSD). Because the AHRQ review only incorporated studies related to SGAs, the authors did not include randomized trials that only studied first-generation antipsychotics (FGAs). The authors also excluded post-hoc analyses of pooled data and randomized trials that addressed acute use of intramuscular antipsychotic agents for the treatment of agitation. Observational studies, including administrative database studies, were included if they had a sample size of at least 500 individuals and addressed antipsychotic treatment of BPSD or harms of antipsychotic treatment in geriatric populations with or without dementia.

Results of this second search included all relevant articles that had been identified in the AHRQ review or in the initial search. Overall, 45 randomized controlled trials and 52 observational studies met the above criteria and were included in the guideline. An additional 4 studies appeared to meet these criteria upon screening the article title, but no abstracts were available and the full article could not be located. An additional 382 articles were related to dementia and antipsychotic treatment but did not meet the criteria noted above. Of these, 46 were meta-analyses or post-hoc analyses of pooled data and 13 were randomized controlled trials that only included an FGA. The remaining articles included 359 that were related to antipsychotic treatment but not dementia, 317 related to dementia but not antipsychotic treatment, and 560 that were unrelated to either dementia or antipsychotic treatment.

## Number of Source Documents

Overall, 45 randomized controlled trials and 52 observational studies met the inclusion criteria and were included in the guideline. See the "Description of Methods Used to Collect/Select the Evidence" above for additional information as well as the supplemental data (see the "Availability of Companion Documents" field) for a flow chart on the article selection.

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Rating the Strength of Supporting Research Evidence

High (denoted by the letter *A*) = High confidence that the evidence reflects the true effect. Further research is very unlikely to change confidence in the estimate of effect.

Moderate (denoted by the letter *B*) = Moderate confidence that the evidence reflects the true effect. Further research may change confidence in the estimate of effect and may change the estimate.

Low (denoted by the letter *C*) = Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is likely to change the estimate.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

"Strength of supporting research evidence" describes the level of confidence that findings from scientific observation and testing of an effect of an intervention reflect the true effect. Confidence is enhanced by factors such as rigorous study design and minimal potential for study bias. Three ratings are used: high, moderate, and low (see the "Rating Scheme for the Strength of the Evidence" field).

Ratings are determined by the Systematic Review Group, after assessment of available clinical trials across four primary domains: risk of bias, consistency of findings across studies, directness of the effect on a specific health outcome, and precision of the estimate of effect.

## Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

This guideline was developed using a process intended to meet standards of the Institute of Medicine (2011). The process is fully described in a document available on the [American Psychiatric Association \(APA\) Web site](#)  (see also the "Availability of Companion Documents" field).

### Guideline Writing Group Composition

The Guideline Writing Group was initially composed of eight psychiatrists with general research and clinical expertise. To achieve a multidisciplinary group, some experts from other disciplines (i.e., nursing, neurology, and geriatrics) were added to the group. In addition, individuals nominated as experts on the topic were surveyed, as described under the section "Expert Opinion Survey Data: Results" in Appendix B of the original guideline document. The Guideline Writing Group was diverse and balanced with respect to its members' expertise as well as other characteristics, such as geographical location and demographic background. Methodological expertise (i.e., with respect to appraisal of strength of research evidence) was provided by the Systematic Review Group. The Alzheimer's Association was involved in reviewing the

draft and provided perspective from patients, families, and other care partners.

### Expert Opinion Data Collection

An expert opinion survey was fielded to 593 experts on the topic of the guideline. These experts were peer-nominated by current and past APA Council and work group members, chairs of academic departments of psychiatry, directors of psychiatry residency programs in the United States and Canada, leadership of other medical organizations, and the APA Assembly. Nominators were asked to identify two types of experts to serve on the panel: researchers and clinicians. "Research experts" were defined as individuals who have significant research activities, scholarly publications, or academic reputation in the treatment of Alzheimer's disease and other dementias, including the use of antipsychotic medications for the treatment of behavioral/psychological symptoms. "Clinical experts" were defined as individuals who have substantial clinical experience in the treatment of Alzheimer's disease and other dementias, including the use of antipsychotic medications for the treatment of behavioral/psychological symptoms. The experts were contacted via email to complete the survey online.

Survey questions were adapted from clinical questions developed by the Agency for Healthcare Research and Quality (AHRQ) for its 2011 review on off-label use of antipsychotics. The survey included questions to address appropriate antipsychotic use, duration of treatment, and clinical experience of using antipsychotics to treat agitation or psychosis in patients with dementia in given clinical circumstances.

Most of the experts, 66.2%, were nominated once, 14.7% were nominated twice, and the remainder were nominated up to 19 times. The composition of the portion of the experts who responded to the survey corresponds closely with that of the entire panel, within 0% to 5% (i.e., in the number of times panel members were nominated and whether they were identified as clinical or research experts or both).

The response rate for the survey was 34.4% (n=204); 3.9% of the responses were partial, meaning that at least one question was completed. The experts who responded to the survey comprised approximately 61% clinical experts, 11% research experts, 24% experts in both categories, and 4% unspecified experts.

Quantitative data from the survey are shown in the section "Review of Supporting Research Evidence" in Appendix A of the original guideline document. The survey also collected many free text comments, which were reviewed during development of the draft guideline. Key themes from qualitative data have been incorporated into the implementation section of the guideline.

### Rating the Strength of Recommendations

Each guideline statement is separately rated to indicate strength of recommendation and strength of supporting research evidence.

"Strength of recommendation" describes the level of confidence that potential benefits of an intervention outweigh potential harms. This level of confidence is informed by available evidence, which includes evidence from clinical trials as well as expert opinion and patient values and preferences. This rating is a consensus judgment of the authors of the guideline and is endorsed by the APA Board of Trustees.

There are two possible ratings: recommendation or suggestion. These ratings correspond to ratings of "strong" or "weak" (also termed "conditional") as defined under the GRADE (Grading of Recommendations Assessment, Development and Evaluation) method for rating recommendations in clinical practice guidelines (described in publications such as Guyatt et al. 2008 and others available on the website of the GRADE Working Group at <http://gradeworkinggroup.org> ). See the "Rating Scheme for the Strength of the Recommendations" field.

When a negative statement is made, ratings of strength of recommendation should be understood as meaning the inverse of the above (e.g., "recommendation" indicates confidence that harms clearly outweigh benefits).

When there is insufficient information to support a recommendation or a suggestion, a statement may be made that further research about the intervention is needed.

The Guideline Writing Group determined ratings of strength of recommendation by a modified Delphi method using blind, iterative voting and discussion. In weighing potential benefits and harms, the group considered the strength of supporting research evidence, the results of the expert opinion survey, and their own clinical experiences and opinions. For recommendations, at least 9 of the 10 members of the group must have voted to "recommend" the intervention or assessment after four rounds of voting. On the basis of the discussion among the members of the group, adjustments to the wording of recommendations could be made between voting rounds. If this level of consensus was not achieved, the group could agree to make a "suggestion" rather than a recommendation. No suggestion or statement was made if three or more group members voted "no statement." Differences of opinion within the group about ratings of strength of recommendation, if any, are described in the section "Potential Benefits and Harms" in the original guideline document.

## Rating Scheme for the Strength of the Recommendations

### Rating the Strength of the Recommendations

"Recommendation" (denoted by the numeral 1 after the guideline statement) indicates confidence that the benefits of the intervention clearly outweigh the harms.

"Suggestion" (denoted by the numeral 2 after the guideline statement) indicates uncertainty (i.e., the balance of benefits and harms is difficult to judge, or either the benefits or the harms are unclear).

## Cost Analysis

The costs of assessment, treatment planning, and discussions with patients, family, or other surrogate decision makers relate to clinician time. Discussions with family or surrogate decision makers can also introduce direct or indirect costs to those individuals (e.g., lost work time, transportation). The feasibility of any treatment must also consider the unique situation of the patient and family, such as access to transportation, insurance status and coverage for specific services, and the effects of treatment requirements on the caregiver's time or employment.

A small number of studies on the cost-effectiveness of behavioral treatments have consistently shown modest but favorable results for specific interventions. Prospective cost estimates for specific patients must take into account the need for individual therapists, the number and duration of required sessions, and the costs of home visits for community-based interventions. Typically, such expenses have been assessed in terms of increased patient activities in the same setting and associated increases in personnel-related costs, but have not been weighed against the cost of pharmacological interventions, the cost of institutionalization for patients who cannot be managed at home or in less restrictive settings, or the cost of injuries to patients and caregivers during episodes of agitated or aggressive behavior.

The Clinical Antipsychotic Trials of Intervention Effectiveness for Alzheimer's Disease (CATIE-AD) trial examined the cost-effectiveness of antipsychotic treatment for outpatients with Alzheimer's disease and psychosis, aggression, or agitation. Although individuals treated with a second-generation antipsychotic (SGA) showed no difference in quality adjusted life years or functional measures as compared with individuals receiving placebo, there were significantly lower costs in the placebo group. However, with the availability of generic SGAs, the costs of medication are likely to be less. The Guideline Writing Group is not aware of studies on the cost-effectiveness of antipsychotic treatment for individuals with dementia in inpatient or nursing facilities or for severely agitated or aggressive individuals who require constant supervision.

## Method of Guideline Validation

External Peer Review



## Description of Method of Guideline Validation

### External Review

This guideline was made available for review on July 31, 2015 by stakeholders, including the American Psychiatric Association (APA) membership, scientific and clinical experts, allied organizations (including patient advocacy organizations), and the public. A total of 44 individuals and 11 groups/organizations submitted comments on the guideline. The chair and co-chair of the Guideline Writing Group reviewed and addressed all comments received; substantive issues were reviewed by the Guideline Writing Group.

### Approval

The guideline was approved by the APA Board of Trustees on December 13, 2015.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The second section of the Practice Guidelines provides a detailed review of the evidence for all guideline statements in accord with national guideline development standards.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Accurate evaluation and appropriate management of patients with dementia accompanied by agitation or psychosis

Refer to the "Potential Benefits and Harms" section in the original guideline document for a discussion of specific benefits and balancing of benefits and harms in rating the strength of recommendations.

### Potential Harms

Adverse effects of interventions, including medication

Refer to the "Potential Benefits and Harms" section in the original guideline document for a discussion of specific harms and balancing of benefits and harms in rating the strength of recommendations.

## Qualifying Statements

### Qualifying Statements

#### Proper Use of Guidelines

The American Psychiatric Association (APA) Practice Guidelines are assessments of current scientific and clinical information provided as an educational service. The guidelines 1) should not be considered as a statement of the standard of care or inclusive of all proper treatments or methods of care; 2) are not continually updated and may not reflect the most recent evidence, as new evidence may emerge between the time information is developed and when the guidelines are published or read; 3) address only the question(s) or issue(s) specifically identified; 4) do not mandate any particular course of medical care; 5) are not intended to substitute for the independent professional judgment of the treating provider; and 6) do not account for individual variation among patients. As such, it is not possible to draw conclusions about the effects of omitting a particular recommendation, either in general or for a specific patient. Furthermore, adherence to these guidelines will not ensure a successful outcome for every individual, nor should these guidelines be interpreted as including all proper methods of evaluation and care or excluding other acceptable methods of evaluation and care aimed at the same results. The ultimate recommendation regarding a particular assessment, clinical procedure, or treatment plan must be made by the clinician in light of the psychiatric evaluation, other clinical data, and the diagnostic and treatment options available. Such recommendations should be made in collaboration with the patient, whenever possible, and incorporate the patient's personal and sociocultural preferences and values in order to enhance the therapeutic alliance, adherence to treatment, and treatment outcomes. For all of these reasons, APA cautions against the use of guidelines in litigation. Use of these guidelines is voluntary. APA provides the guidelines on an "as is" basis and makes no warranty, expressed or implied, regarding them. APA assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of the guidelines or for any errors or omissions.

#### Limitations of the Evidence in Assessing Benefits and Harms

In assessing the balance between the benefits and harms of these recommendations, there are a number of factors to note. As knowledge of dementia and its treatment evolve, there may be shifts in the balance of benefits and harms for these recommendations. At present, however, studies are either not available or not designed to give precise guidance on many of the clinical questions. One example is the lack of studies that examine benefits of assessment or discussion with patients, surrogate decision makers, families, and others. Another example is the small number of head-to-head trials comparing different pharmacological and nonpharmacological treatments for agitation or psychosis in dementia and an even fewer number of trials with parallel placebo or sham treatment arms. With nonpharmacological interventions, there can be significant variations in methodology from study to study, and multiple interventions can be administered together, confounding the interpretation of findings. Trials often fail to examine quality of life or other outcomes that patients and families view as most important. Studies also have not assessed the optimal time at which an attempted tapering of antipsychotic medication is indicated. There is insufficient evidence to determine whether individuals with more severe dementia, psychosis, or agitation will have a greater risk of relapse with antipsychotic discontinuation. In terms of monitoring, studies have not examined optimal timing of assessment during antipsychotic treatment or after an attempt at tapering antipsychotic treatment. The optimal frequency of laboratory and physical assessments to detect metabolic or other side effects of treatment also requires study in patients with dementia. It is also not clear whether laboratory data or other findings could predict which patients are at the highest risk of stroke or mortality or whether other interventions could reduce such risks.

Other aspects of research design may introduce variability into the findings and affect the ability to compare studies. A key issue is the way in which behavioral and psychological symptoms are defined and measured, with the definition and measurement of agitation being particularly problematic. Rating scales for behavioral and psychological symptoms define and measure agitation and aggressive behaviors in different ways and often mix measures of symptom frequency with measures of severity. New, shorter scales are also needed for routine clinical use. When studies have examined adverse effects of antipsychotic treatment in patients with specific subtypes of dementia, these diagnoses are generally based on clinical grounds, and this can introduce substantial variability as compared with diagnoses established through structured criteria, biomarker confirmation, or neuropathology. Studies with heterogeneous samples may fail to find a benefit or harm of a specific treatment, even if one is present for a more homogeneous subset of the patients.

As another source of variability, patients with dementia who are enrolled in clinical trials are not likely to be representative of the full range of individuals for whom clinical use of an antipsychotic medication might be considered. Significant physical illness (e.g., cardiopulmonary or renal impairments, cancer), use of certain medications (e.g., anticoagulants), or severe aggression requiring emergent intervention will typically exclude a subject from such research. Other psychiatric disorders, including substance use disorders, are also common exclusion criteria. It is not clear whether these typical exclusion criteria or other factors contribute to the apparent mismatch between clinicians' views of antipsychotic benefits and the limited benefits found in clinical trials. Nonetheless, these limitations of existing clinical trials make it hard to draw precise conclusions about the likely benefits of treatment for an individual patient.

In terms of harms data, typical administrative database studies are unable to show the temporal sequence between treatment and a specific outcome. Thus, an individual with dementia may fracture a hip, become delirious, and receive antipsychotic medication. An administrative database study would associate the hip fracture or a subsequent pulmonary embolus with antipsychotic medication even without a causal relationship. Alternatively, the presence of psychiatric symptoms such as agitation may result in both a greater risk of falls and an increased likelihood of receiving an antipsychotic medication. In the future, prospective collection of harms data using registry reporting or electronic health record data analytics may help delineate the temporal sequence of antipsychotic use and adverse outcomes.

## Implementation of the Guideline

### Description of Implementation Strategy

#### Implementation

Refer to the original guideline document for discussion of implementation considerations and suggestions for the following:

- Assessment of behavioral/psychological symptoms of dementia
- Development of a comprehensive treatment plan
- Assessment of benefits and risks of antipsychotic treatment for the patient
- Dosing, duration, and monitoring of antipsychotic treatment
- Use of specific antipsychotic medications, depending on clinical context

#### Quality Measurement Considerations

Refer to the original guideline document for discussion of quality measures considerations and suggestions for the following:

- Existing measures of relevance to antipsychotic use in individuals with dementia
- Variability in practice that may be addressed by quality measures
- Potential options for measure development
- Practical barriers to measure development
- Additional uses of guideline recommendations to enhance quality

### Implementation Tools

Audit Criteria/Indicators

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

American Psychiatric Association (APA). The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. Arlington (VA): American Psychiatric Association (APA); 2016. 210 p. [209 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2016

### Guideline Developer(s)

American Psychiatric Association - Medical Specialty Society

### Source(s) of Funding

American Psychiatric Association (APA)

### Guideline Committee

Guideline Writing Group

Systematic Review Group

American Psychiatric Association (APA) Steering Committee on Practice Guidelines

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## Financial Disclosures/Conflicts of Interest

### Management of Potential Conflicts of Interest

Members of the Systematic Review Group and Guideline Writing Group members were required to disclose all potential conflicts of interest before appointment, before and during guideline development, and on publication.

Refer to the "Disclosures" section in the original guideline document for a list of disclosures.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the [PsychiatryOnline Web site](#) .

## Availability of Companion Documents

The following are available:

Dementia and antipsychotic treatment: literature search strategies. Online supplement. Arlington (VA): American Psychiatric Association (APA); 2016. 137 p. Available from the [PsychiatryOnline Web site](#) .

The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. Executive summary. Arlington (VA): American Psychiatric Association (APA); 2016. 4 p. Available from the [PsychiatryOnline Web site](#) .

Practice guidelines on the use of antipsychotics to treat agitation and psychosis in patients with dementia. CME course. Available from the [American Psychiatric Association Web site](#) .

New development process for practice guidelines of the American Psychiatric Association. Arlington (VA): American Psychiatric Association (APA); 2011 Dec 20. 16 p. Available from the [PsychiatryOnline Web site](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on September 26, 2016. The information was updated by the guideline developer on October 21, 2016.

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